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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BRIAN ROFFE, ESQ 11 SUNRISE PLAZA, SUITE 303 VALLEY STREAM, NY 11580-6111			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT 3736	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,366

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 33-54 is/are pending in the application.
- 4a) Of the above claim(s) 5, 15 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-14, 16-22 and 34-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 11/19/2007, amended claim(s) 1, 3-6, 9, 12-14, 17-19, 35, 37, 39, 42, 44, 46-49, and 52 is/are acknowledged. The current rejections of the claim(s) 1-4, 6-14, 16-22, and 34-54 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Objections

2. Claim 2 is objected to because of the following informalities: the positive recitation of "the anus" in lines 4-5 should apparently read "an anus". Appropriate correction is required.

3. Claim 2 is objected to because of the following informalities: the positive recitation of "the rectum" in line 4 should apparently read "a rectum". Appropriate correction is required.

4. Claims 6, 9, 17, 18, 39, and 42 are objected to because of the following informalities: the positive recitation (or similar recitation) of "wherein said distal portion has first and second arms connected to said expanded portion of said body, said first arm defining said first lumen and said opening of said first lumen, said second arm defining said second lumen and said opening of said second lumen" should apparently read "wherein said distal portion has first and second arms connected to said expanded portion of said body, said first arm defining said second lumen and said opening of said second lumen, said second arm defining said third lumen and said opening of said third

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lumen" (or the like). See specification page 14 lines 14-28. Appropriate correction is required.

5. Claim 9 is objected to because of the following informalities: the positive recitation of "a pressure relief valve arranged in connection with said third lumen" in lines 6-7 should apparently read "a pressure relief valve disposed in said third lumen". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-4, 6-11, 13, 14, 16-22, 35-45, and 48-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 13 and 35 and those depending therefrom contain within their scope the positive recitation of "regulating means arranged partially within said third lumen" which is not enabled by the disclosure. As evidenced by at least Figure 11 and described in the Specification (see page 14 line 24 – page 15 line 4), the "regulating means" is disposed and/or "arranged" entirely within said third lumen and thus cannot be "arranged at least partially within said third lumen".

8. Claims 12, 34, 46, and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 12 and those depending therefrom contain within their scope the positive recitation of "a signal indicator device arranged at least partially *within* said body" which is not enabled by the disclosure. As evidenced by at least Figures 11 and 12 and described in the Specification (see page 14 line 24 – page 15 line 4), the "signal indicator device" is "arranged" as an extension of the body and thus cannot be "arranged at least partially *within* said body".

9. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 43 positively recites "said regulating means comprise a component having upper and lower flaps" which is not enabled by the disclosure. As evidenced by at least Figures 11 and described in the Specification (see page 14 line 24 – page 15 line 4), the "regulating means" is a pressure release valve disposed within the third lumen of the second distal arm and is not the signal indicator having "upper and lower flaps".

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 7, 14, 16, 41, 51 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for duplicating essential elements, such duplication amounting to an indeterminate scope of/between the elements. See MPEP § 2172.01. The duplicated elements are: “a constriction” and “regulating means”. The “constriction” and the “regulating means” appear to be duplicated structural limitations that render the claims indefinite. See Figures 11 and 12 and the Specification page 13 line 25 – page 14 line 28.

13. Claims 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for duplicating essential elements, such duplication amounting to an indeterminate scope of/between the elements. See MPEP § 2172.01. The duplicated elements are: “an expanded portion” and “insertion and sealing means”. The “expanded portion” and the “insertion and sealing means” are duplicated structural limitations that render the claims indefinite. See Figures 11 and 12 and the Specification page 13 line 25 – page 14 line 28.

14. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the generating an “audible indication” and the structure responsible therefor. As claimed no structural element is recited that may provide an “audible indication” and

it is unclear how, in the absence of a sound generating structure, when a specific air pressure in the patient's GI tract is reached and air is released via the regulating means an audible indication is generated.

15. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for duplicating essential elements, such duplication amounting to an indeterminate scope of/between the elements. See MPEP § 2172.01. The duplicated elements are: "insertion-limiting means for limiting insertion" and "insertion and sealing means". The "insertion-limiting means for limiting insertion" and the "insertion and sealing means" are duplicated structural limitations that render the claims indefinite. See Figures 11 and 12 and the Specification page 13 line 25 – page 14 line 28.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1-4, 6-14, 16-22, 34-42, 44, 50, 51, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Doi et al. (US 4,971,034, hereinafter Doi).

18. Doi discloses an air introduction device (Abstract), comprising:

- a body (as best seen in Figures 1, 6, 9, and 11) defining an interior space (the interior volume defined by the body structure), having a proximal portion adapted to be inserted into a patient's gastrointestinal tract (32) (column 9 lines 28-30) and a distal portion adapted to mate with an air inflation device (20) to enable air flow

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through said body into the gastrointestinal tract when said proximal portion is inserted into the patient's gastrointestinal tract (column 2 lines 29-36 and column 9 lines 28-47),

- the body defining first (the lumen of 31), second (the lumen of 19), and third (the lumen of 26) lumens communicating with said interior space, each extending from said interior space in a different direction to provide three different, non-overlapping flow paths to and from said interior space (as best seen in Figures 1, 6, 9, and 11), and each having an opening where the opening of said first lumen is at an outermost end of said first lumen (as best seen in Figures 1, 6, 9, and 11), the opening of said second lumen is at an outermost end of said second lumen (as best seen in Figures 1, 6, 9, and 11), and the opening of said third lumen is at an innermost end of said third lumen (as best seen in Figures 1, 6, 9, and 11);
- a signal indicator device (225) arranged at least partially in and fixed to said third lumen of said body and arranged to generate a signal (224) when a specific air pressure in the patient's gastrointestinal tract is reached (column 2 lines 39-43, column 4 lines 32-40, and column 5 lines 8-19), wherein said signal indicator device is arranged to generate an audible indication based on exceeding a predetermined pressure threshold in the patient's gastrointestinal tract (column 20 lines 27-40);
- an insertion and sealing means for enabling insertion (30 and 31) of the proximal portion of said body including said first lumen into an orifice, said insertion and sealing means for enabling insertion comprising an expanded portion (30) that limits insertion depth and a proximal terminus being a rounded or tapered tip having a

smaller cross-section than said proximal portion (as best seen in Figure 1 and 11), and wherein said insertion and sealing means are capable of being inserted an anus of a person such that the anus constricts around said proximal portion and thereby seals said body against an anal wall;

- a coupling means (the coupling of elements 19 and 20) for enabling coupling of said body to said air inflation device via said second lumen such that air is directed from the inflation device into said interior space defined by said body and then from said interior space in a second flow path out of said body through said first lumen into the person's GI tract; and
- a regulating means (37) comprising a pressure relief valve disposed within and in connection with said third lumen of said body for regulating air pressure in the patient's gastrointestinal tract (as best seen in Figures 1 and 3), said regulating means being arranged to release air from the patient's gastrointestinal tract when the air pressure in the patient's bowel exceeds a predetermined pressure (column 2 lines 39-43, column 4 lines 32-40, column 5 lines 8-19, and column 10 lines 2-13) such that the air being released flows backward in the second flow path through said first lumen into said interior space and then from said interior space in the third flow path out of said body through said third lumen,
- wherein said expanded portion (30) is interposed between said proximal portion and said distal portion and adapted to engage with a body opening to limit insertion of said proximal portion into the patient's gastrointestinal tract, has a larger diameter than the proximal portion including a circular portion having a largest diameter of

said expanded portion and which uniformly extends beyond an outer periphery of said proximal portion around the entire periphery of said proximal portion, a first truncated conical surface tapering from said largest diameter circular portion to said proximal portion and a second truncated conical surface tapering from said largest diameter circular portion to said distal portion (as best seen in Figures 1, 5, 6, and 9),

- wherein said distal portion has first and second arms, said first arm (19) defining a first lumen (the volume defined by element 19) with a distal opening that is adapted to mate with a connector of the air inflation device, said second arm (28) defining a second lumen (the volume defined by element 28) with a distal opening, wherein said first and second arms are connected to said expanded portion of said body,
- wherein said pressure relief valve is arranged in said second lumen for releasing air when a specific air pressure in the rectum is reached (column 10 lines 2-49), the outlet of said pressure relief valve communicates with the ambient atmosphere (column 16 lines 46-50), and the pressure relief valve comprises a constriction,
- wherein said signal indicator device is arranged in operative connection with said second arm in order to indicate via audible alarm an exceeded predetermined pressure threshold therein, and
- wherein said proximal portion and said expanded portion have a common central axis and said second arm of said distal portion has a central axis parallel to said common central axis of said proximal portion and said expanded portion (as best seen in Figure 1).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Doi. Doi discloses the claimed invention but does not disclose expressly the audible signal indicator device comprising upper and lower flaps. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the air introduction device as taught by Doi with the audible signal indicator device comprising upper and lower flaps, because Applicant has not disclosed that audible signal indicator device comprising upper and lower flaps provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the signal indicator device comprising an alarm light and an alarm buzzer (column 20 lines 27-40) as taught by Doi, because it provides an audible signal indication to medical personnel that the insufflation pressure is exceeding a predetermined pressure threshold and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Doi. Therefore, it would have been an obvious matter of design choice to modify Doi to obtain the invention as specified in the claim(s).

21. Claims 45-49, 52, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doi in view of Jones et al. (US 2003/0120169 A1, hereinafter Jones).

Doi discloses the claimed pressure monitoring invention except for explicitly disclosing the body being a monolithic, single-member, and made of an elastomer material. Jones teaches a pressure monitoring device (10 or 100) having a monolithic, single-member, and elastomer body (as best seen in Figures 1 and 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pressure monitoring device as taught by Doi, with the pressure monitoring device as taught by Jones for the purpose of configuring a pressure monitoring device.

Response to Arguments

22. Applicant's arguments with respect to claims 1-4, 6-14, 16-22, and 34-54 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./

Jeff Hoekstra

Examiner, Art Unit 3736

